

Abbreviated Study Title: LASST

**Nemours**  
**Parental Permission for**  
**Participation in a Research Study**  
*Template Version February 2014*

You have been asked to permit your child to be in a research study. This form explains the research, your child's rights as a research participant, and any responsibilities that you may have as a result of your child's participation. You should understand the research study before you agree to permit your child to be in it. Read this permission form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.

**1. WHAT IS THE TITLE OF THE STUDY?**

Long-Acting Beta Agonist Step Down Study (LASST)

**2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?**

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

	<b>Nemours – Jacksonville</b>	<b>Nemours - Orlando</b>	<b>Nemours - Delaware</b>
<b>Principal Investigator</b>	Kathryn Blake, Pharm.D.		
<b>Co-Investigators</b>	John J. Lima, Pharm.D.	Jason E. Lang, M.D. Floyd Livingston, M.D.	Aaron Chidekel, M.D..
<b>Address</b>	Nemours Children's Clinic 807 Children's Way Jacksonville, FL 32207	Nemours Children's Clinic 1717 South Orange Ave. Suite 100 Orlando, FL 32806-2946  Nemours Children's Hospital Department of Pulmonology 13535 Nemours Parkway Orlando, FL 32827	Alfred I. duPont Hospital for Children 1600 Rockland Rd. Wilmington, DE 19803
<b>Daytime Phone</b>	(904) 697-3529	(407) 650-7175 (407) 650-7634	(302) 651- 6400
<b>After Hours Phone</b>	(904) 697-3600	(407) 650-7000	(302) 651-4000
<b>Long Distance</b>	1-800-SOS-KIDS 1-800-767-4357		

**3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?**

If you have questions about your child's rights as a research subject, what to do if your child is injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Tim Wysocki, PhD, Chairperson, Nemours IRB 2 at (904) 697-3415.

Paul Garfinkel, MSH, Director, Nemours Office for Human Subjects Protection, at (904) 697-4023.

Email address: [NOHSP@nemours.org](mailto:NOHSP@nemours.org)



#### 4. WHAT IS THE PURPOSE OF THE STUDY?

Current asthma guidelines recommend decreasing medication once asthma is controlled for at least 3 months, but there is no agreement on the best way to decrease the medication(s). This research is being done to test what is the best approach to decreasing asthma medications for patients whose asthma is well controlled on a combination of medications that include an inhaled corticosteroid (ICS) and a long-acting beta agonist (LABA),

Examples of combination medications include Advair®, Symbicort®, and Dulera®.

Inhaled corticosteroids include fluticasone (Flovent®), mometasone (Asmanex®), ciclesonide (Alvesco®) and budesonide (Pulmicort®).

Long-acting beta agonists include salmeterol (Serevent®) and formoterol (Foradil® or Perforomist®).

This study will test two ways of decreasing medication:

(1) reducing the dose of (ICS) while keeping the LABA dose the same

or

(2) completely stopping the (LABA) while keeping the (ICS) dose the same.

In addition, one group of participants will not decrease their medications. All of the drugs that will be tested in this study are approved by the U.S. Food and Drug Administration (FDA) for treatment of asthma.

#### 5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

American Lung Association is the sponsor of this study. GlaxoSmithKline will provide the study drug and funding to conduct this study.

#### 6. WHO CAN BE IN THE STUDY?

Children ages 12 to 17 years will be recruited for this study. Your child is being asked to participate in the study because he/she has physician diagnosed asthma that is well controlled on a combination of inhaled corticosteroids (ICS) and long-acting beta agonists (LABA). The study doctor will tell you if there are any reasons why your child could not be in the study.

#### 7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

Overall about four hundred and fifty (450) people will be enrolled in this study. Participants will be enrolled at 18 clinical centers in the United States. We will enroll up to 90 participants at Nemours.

#### 8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation will last 56 weeks (about 13 months) with a total of 11 study visits and 1 telephone visit. Study visits range from 2 to 4 hours; most will last approximately 2 hours.

#### 9. WHAT ARE THE RESEARCH PROCEDURES?

Your child will be asked to take a study treatment for asthma every day for the entire study (56 weeks). Participation in this study is not meant to replace usual care for your child's asthma. You should inform your child's primary asthma care doctor of their participation in the study. We will send your child's primary asthma care doctor a letter to notify them of your child's participation in the study. If at any time during the study he/she has poor asthma control and needs additional care, your child's primary asthma care doctor will be notified. Your child cannot be in this study unless he/she has a source for asthma care other than this research



Abbreviated Study Title: LASST

study. If your child does not have a place to get asthma care and you or your child ask us, we will refer your child to a place where asthma care is provided.

At the first three visits your child will undergo a number of procedures to see if they are eligible for the study and to record how their asthma is doing. During that time all study participants will take the same treatment for asthma. The treatment is Advair 250/50, a combination of an inhaled corticosteroid and a long-acting beta agonist (fluticasone/salmeterol 250/50 mcg). Your child will be asked to take 1 inhalation of the combination medication from a diskus inhaler twice a day.

At the third visit, if your child's asthma is well controlled, they will be randomly assigned (by chance like drawing a number out of a hat) to receive one of the three study treatments for the rest of the study. The three study treatments are:

- 1) Advair 250/50, 1 inhalation twice a day (same as during the first part of the study)
- 2) Advair 100/50, 1 inhalation twice a day (lower dose of inhaled corticosteroid)
- 3) Flovent (Fluticasone) 250 1 inhalation twice a day (no long-acting beta agonist)

They will have an equal chance of receiving one of the three treatments. Neither you nor the study doctor or study staff will know to which treatment your child is assigned, but this information can be obtained if medically necessary. After your child completes the study, you will be told which treatment they received.

Your child will be asked to come in for 11 clinic visits, and participate in one telephone visit over a 56 week period. Each visit to the clinic will take between 2 and 4 hours to complete. The telephone visit should take fewer than 15 minutes.

The schedule of visits is shown below:

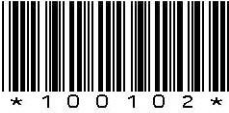
**Schedule**

<u>Visit Number</u>	<u>Visit Type</u>	<u>Weeks after previous visit</u>
Visit 1	Screening	-----
Visit 2	Stable Phase	4 weeks after Visit 1
Visit 3	Random Assignment	4 weeks after Visit 2
Phone Visit 4	Telephone Contact	3 weeks after Visit 3
Visit 5	Follow-up	3 weeks after Phone Visit 4
Visit 6	Follow-up	6 weeks after Visit 5
Visit 7	Follow-up	6 weeks after Visit 6
Visit 8	Follow-up	6 weeks after Visit 7
Visit 9	Follow-up	6 weeks after Visit 8
Visit 10	Follow-up	6 weeks after Visit 9
Visit 11	Follow-up	6 weeks after Visit 10
Visit 12	Final Follow-up	6 weeks after Visit 11

**Study Procedures:**

Your child will have several tests at each visit. Some of them will be done more than once. A description of each test follows.

- Spirometry is a test that measures how well your child is able to breathe. He/she will wear a nose clip and breathe out forcefully into a machine that measures how much air he/she can blow out and how fast it comes out. He/she will do this before and after inhaling a bronchodilator medication to see if the

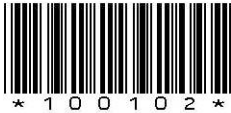


Abbreviated Study Title: LASST

medication improves his/her test results. The bronchodilator is Albuterol. Albuterol can help open up the breathing tubes in the lungs of people with asthma. This test will be done at each of the 11 clinic visits.

- Peak Flow Meter: We will give your child a peak flow meter, which is used to test the lungs. To use it, your child will take a deep breath and blow hard and fast into the tube. At the Screening visit (V1) we will show you and your child how to use the peak flow meter and how to read and record the results. If your child cannot use the peak flow meter, your child cannot join the study. Your child will be able to keep the peak flow meter after the study is over.
- Asthma Diary: We will ask you and your child to complete an asthma diary card form daily. On the diary card he/she will record his/her peak flow every morning, his/her asthma symptoms or other symptoms he/she might experience, and whether he/she took the study medication or other asthma medication each day. We will ask you to bring in the completed asthma diaries when you and your child come for each visit. The purpose of this diary is to see how well your child's asthma symptoms are being controlled. Your child will be asked to start keeping a daily asthma diary after the first visit, the Screening visit (V1), until the study is completed, the entire 56 weeks that he/she will be in the study.
- Physical Exam: A brief physical exam, including vital signs will be performed at the first visit, at the Randomization visit (V3), and at 2 follow-up visits. Your child's height and weight will be measured at all clinic visits.
- Medical History: You and your child will be asked a series of questions and will be given several questionnaires about the history of his/her health and asthma at the first study visit, the Screening visit (V1) and questions about the state of his/her health between visits at all other visits. Some questionnaires will ask you and your child about his/her asthma symptoms, cigarette smoke exposure, and females will be asked about menstrual periods.
- Asthma Control Test: Your child will be asked to complete a series of multiple-choice questions about his/her asthma symptoms and daily activities. This will be used to measure his/her asthma control. Your child will complete these questionnaires at all clinic visits.
- Quality of Life Questionnaires: Your child will be asked to complete a series of multiple-choice questions about his/her daily activities and health. This will be used to measure the quality of your child's life as it relates to his/her asthma. Your child will complete these questionnaires at 10 of the 11 clinic visits.
- Exhaled Nitric Oxide: Your child will be asked to take a deep breath in and then blow out all the air slowly into a machine that records the amount of nitric oxide that is in his/her lungs. Nitric oxide is a measure of inflammation in the lungs and gives information about your child's asthma. This test takes about 5 minutes. Your child will be asked to do this at all 11 clinic visits.

Blood draws: 10 mL (about 2 teaspoons) of blood will be obtained from a vein in your child's arm at visit 3. We will use the blood to test to see if your child has allergies. If requested, a numbing cream



Abbreviated Study Title: LASST

can be used to help ease the pain associated with the blood draw. Some of the blood will be saved for possible future tests related to asthma.

- In addition, if you give your permission, an additional 10 mL (about 2 teaspoons) of blood will be drawn and saved for possible future tests related to asthma, including the genes (material that contains information about our ancestors) that may play a role in determining whether someone gets asthma, how severe the asthma may be, and the response to asthma treatments. Donating your child's blood for DNA genetic testing is optional and not required for participation. At the end of the form there is a section that provides more information on future genetic testing.
- Future Research Use of Samples: Any remaining portion of your child's sample will be permanently stored for future research use. These samples and health information about your child might be used by other investigators for research about other diseases related to asthma and allergy. By participating in this study, you are also agreeing to this use of your child's samples
- Pregnancy Testing: Girls who are capable of having children will have a urine pregnancy test at the Screening visit (V1) and the Randomization visit (V3).

### What are The Expectations of You and Your Child in the Study?

If you agree to allow your child to participate in this study, you and your child will be expected to do the following:

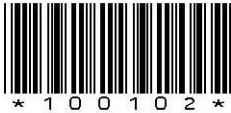
1. Attend all eleven (11) clinic visits during business hours.
2. Your child must take the study medication twice a day, every day for the entire study. You are expected to help your child remember to take his/her study drug.
3. Keep the study medication out of the reach of anyone who is not participating in the study.
4. At each visit, return your child's empty study medication containers and all unused study medications.
5. Your child should record whether they took study medication or other asthma medication, asthma symptoms, and peak flow readings daily on the diary card provided. You must bring your child's diary cards to every visit.

**When should I call the study staff?** Call the study staff for any reason if you feel you need to speak with someone about the study. Possible reasons include the following:

1. If you have any questions or concerns about the study (see front page, Section 2);
2. If your child has had worsening asthma and had to go to a doctor's office or the emergency room or had to be started on prednisone;
3. If your child is experiencing any unusual signs or symptoms, illnesses or injuries, regardless of the cause.
4. If your child has any new medication including over-the-counter medications or medications prescribed by another doctor.

### 10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?

Any research has some risks (things that could make your child sick, make your child feel uncomfortable, or hurt your child). The risks with the most chance of happening to someone in this study are listed below. Also, there is a chance of other risks that almost never happen, or unknown risks.



Abbreviated Study Title: LASST

It is also possible that your child's asthma may not improve or may worsen while being in this study. Uncontrolled asthma may be life-threatening. Increased use of your child's rescue medications is a sign that their asthma may be getting worse. If you feel that their asthma is getting worse, have him/her use their rescue medicine as prescribed by their regular asthma care doctor. Then call their regular asthma care doctor immediately.

**Get emergency medical care if:**

- Your child's breathing problems worsen quickly and
- if your child uses their rescue inhaler medicine, but it does not relieve their breathing problems.

During this study, you and your child will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while your child is in the study, medical information needed for their treatment can be made available to their study doctor and other doctors who treat them.

**Study Treatments**

**Advair (fluticasone/salmeterol):** The most common symptoms reported by patients taking fluticasone/salmeterol treatment were: upper respiratory infections (21% to 27% of participants in earlier studies); inflammation of throat, nose or sinuses (5% to 13%); hoarseness or difficulty speaking (2% to 5%); headache (12% to 13%); oral candidiasis (thrush, a yeast infection in the mouth) (1% to 4%); nausea and vomiting (4% to 6%); other gastrointestinal symptoms (2% to 4%); and muscle or bone pain (2% to 4%). For children, infections in the ear, nose, and throat are common. Less common side effects include serious allergic reactions, sudden breathing problems after inhaling, heart and nervous system effects, reduced adrenal function, changes in blood, weakened immunity, lower bone mineral density, eye problems and slowed growth in children.

**Long-acting beta agonists:** People with asthma who take long-acting beta2-adrenergic agonist (LABA) medicines such as salmeterol (one of the medicines in Advair Diskus), have an increased risk of death from asthma problems. A study done in the US showed an increase risk of asthma-related death in participants receiving salmeterol alone as compared to participants on placebo (no medicine), 10 in 10,000 participants (0.10%) in the group receiving salmeterol compared to 0.02% (2 in 10,000) in the group receiving a placebo. It is not known whether fluticasone propionate, the other medicine in Advair Diskus, reduces the risk of death from asthma problems seen with salmeterol. For this study participants will not receive salmeterol alone.

**Flovent (fluticasone):** The most common symptoms reported by patients taking fluticasone treatment were: upper respiratory infections (25% to 29% of participants in earlier studies); lower respiratory infections (4% to 8%); inflammation of throat, nose or sinuses (1% to 12%); hoarseness or difficulty speaking (1% to 4%); headache (8% to 14%); oral candidiasis (thrush, a yeast infection in the mouth) (2%); nausea and vomiting (1%); other gastrointestinal symptoms (1% to 2%); and muscle or bone pain (3%). Fluticasone has not been associated with an increased risk of death from asthma.

**Ventolin (albuterol):** The most common side effects associated with albuterol are upper respiratory infection (21%), sore throat (14%), Nausea (10%), rhinitis (16%), increased heart rate, tremors (shakes) (7%), chest tightness, dizziness, nervousness (7%), cough (5%), headaches (7%), and sleeplessness. Serious allergic reactions that can be life-threatening are very rare.





Abbreviated Study Title: LASST

- Spirometry: There is little risk from spirometry. Some people occasionally have chest soreness or light-headedness from the hard blowing. The chest soreness usually goes away by itself, but can be relieved with non-prescription pain-relievers.
- Peak Flow Measurement with Peak Flow Meter: Asthma patients commonly use peak flow meter readings to see how their lungs are doing. There is little risk from use of a peak flow meter. Some people may have chest soreness from the hard blowing or light-headedness if they use it standing up. The chest soreness usually goes away by itself, but can be relieved with non-prescription pain-relievers. If your child's gets lightheaded, he/she should perform the peak flow measurements while sitting down.
- Exhaled Nitric Oxide: Measurement of nitric oxide in breath is a simple procedure with little or no risk. It is possible to feel lightheaded if they blow too hard, if your child feels dizzy he/she may take a break. These procedures can be done in a seated position.
- Blood Draw: Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.
- Numbing Cream: A local anesthetic may be used to numb the site of the blood test if requested. If a numbing cream is used, the following side effects may occur: redness, swelling, itching, rash, change in sensation to temperature, and rarely, an allergic reaction.
- DNA testing: Donating blood for additional DNA testing is optional. Every effort will be made to keep the results of the DNA testing on your child's sample confidential. However, there is a very small risk that an unauthorized person may review your child's information. Additional information about measures taken to minimize these risks can be found on the last page of this consent.
- Privacy: There is a risk of loss of privacy and confidentiality when participating in this study. Information for this study will be taken from your child's clinic chart. The measures taken to prevent and minimize these risks are found in Section 19: What information about my child will be used or disclosed?
- Pregnancy: Girls deciding whether or not to be in this study may already have started having periods or may begin having periods while they are in this study. Therefore, we need to tell you some important facts.

We often do not know the effects of research procedures (such as drugs or tests) on unborn babies. The drugs being evaluated in the study have been shown to increase the risk of miscarriage and birth defects in animals. This research may hurt an embryo or fetus in ways we do not currently know. Your child should not plan to become pregnant while participating in this study. If sexually active, your child should use effective birth control to prevent pregnancy while participating in this study. As appropriate, the study doctor will discuss issues of possible sexual activity and use of effective birth control privately with your child. Only girls who are not pregnant will be randomized to study treatment. Girls who are breastfeeding will not be enrolled in this study; the safety of these drugs during breastfeeding is unknown.



Abbreviated Study Title: LASST

Because girls can become pregnant even when using birth control, we will be doing pregnancy tests at the first study visit, and again at visit 3. The results of any pregnancy test done during the study will be made available only to your child. By law, all minors have a right to confidentiality when discussing issues of pregnancy and birth control with a doctor. This information will be discussed with you only if your child agrees. If there is any chance that pregnancy could have occurred during the study, the study doctors must be told immediately. Anyone who is pregnant may be taken out of the study right away. You and your daughter should be aware that, if this happens, others are likely to realize that she is pregnant. We encourage open honest communication between parents and their children regarding issues of sexual activity and possible pregnancy. It is also important for you to let the study doctor know if a young girl starts having periods during this study so that appropriate precautions can be taken from that point onward.

#### **11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

There may be no direct benefit to your child from taking part in the study. Your child may experience an improvement in asthma control. Your child will receive an assessment of his/her general health and asthma. Your child will also receive a peak flow meter.

You and your child may feel better knowing that by being in this study, you may help others with asthma. The information from this study may be helpful in the future to other people with asthma.

#### **12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?**

Nemours will assure that your child receives treatment, if needed, for study related injuries. Neither Nemours, the American Lung Association, GlaxoSmithKline, nor the study doctor have a program to pay for medical care provided to treat the injury and are not responsible. If you have health insurance, it may, or may not pay for the cost of treatment resulting from a study-related injury. If your insurance does not pay, you understand that you will be responsible for paying for the cost of treatment. If your insurance does not pay for study-related injury, or if you do not have insurance, you will be responsible for paying for the cost of treatment.

If you think that your child has been injured while in this study or has a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor's names and phone numbers are on the first page of this form.

If you or your child has a question or problem related to the study, you can call the principal investigator, Dr. Kathryn Blake, the study coordinator, or the study staff anytime. The study staff is available Monday-Friday from 8:00am to 5:00pm. During these hours, you should call (904)-697-3529 for medical advice.

During evenings, weekends, and holidays, you should call (904)-697-3600 or (800) SOS-KIDS (Nemours-Long Distance Operator). You will reach the Nemours operator. Ask to page/call the nurse/coordinators.

#### **13. IS BEING IN THE STUDY VOLUNTARY?**

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your child's usual medical care if you or your child decide not to be in the study or decide to stop being in the study. No one will be angry with you or your child, or treat your child any differently than before your child was asked to be in the study.

If you withdraw your child from this study, your child may continue treatment with his/her doctor, or you may seek treatment for your child from another doctor of your choice. In the event that you withdraw your child from





Abbreviated Study Title: LASST

the study, Nemours may use or give out your health information that it already has, and all clinical data related to the study may continue to be collected from your child's medical records, if the information is needed for this study or any follow-up activities.

**14. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?**

You can refuse to permit your child to participate in this study. There may be other research or treatment choices that could be considered for your child.

The study doctor can provide detailed information about the benefits and risks of the various treatment options available to your child. You should feel free to discuss these alternatives with the study doctor. In addition, your child's doctor can prescribe any of the study medications for you even if you do not join the study.

**15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?**

Your child may be taken out of the study if:

- Staying in the study would be harmful.
- Your child needs treatment not allowed in the study.
- You or your child fails to follow instructions.
- Your daughter becomes pregnant.
- The study is cancelled.
- There may be other reasons to take your child out of the study that we do not know at this time.

We will continue to ask your child to come in for study visits even if he/she stops taking the study medication, however, your child may stop participating at any time.

**16. WHAT ARE THE COSTS OF BEING IN THIS STUDY?**

There will be no cost for your child's participation in this study.

**17. WILL PEOPLE BE PAID FOR BEING IN THIS STUDY?**

No arrangement exists that would allow participants to share in any profit generated from this study or future research. Your child will be paid up to \$825 for taking part in this study. Your child will receive payment for each visit except for the phone visit. If you or your child decide that he/she should leave the study before finishing all visits, your child will be paid for the visits he/she has completed. We also offer the opportunity for students to earn community service hours for participating in this study; our staff will be pleased to complete the required paperwork.

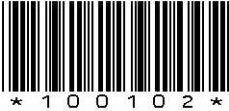
<u>Visit</u>	<u>Payment</u>
Visit 1	\$50.00
Visit 2	\$25.00
Visit 3	\$75.00
Phone Visit 4	\$0.00
Visit 5	\$75.00
Visit 6	\$75.00
Visit 7	\$75.00
Visit 8	\$75.00
Visit 9	\$75.00
Visit 10	\$75.00



Approved by the Nemours IRB:

Valid from: 09/04/2015 through 09/03/2016

IRB# JAX: 288148



Abbreviated Study Title: LASST

Visit 11	\$75.00
Visit 12	\$150.00
Total	\$825

## 18. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO PERMIT MY CHILD TO STAY IN THE STUDY?

Any new information that may change your mind about allowing your child to be in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while your child is taking part in this study, it will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you or your child. At most, the web site will include a summary of the results. You can search this web site at any time.

## 19. WHAT INFORMATION ABOUT MY CHILD WILL BE USED OR DISCLOSED?

Identifiable health information about your child will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for research use and disclosure of health information that includes "identifiers" that can connect the health information to your child. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This Identifiable health information is called Protected Health Information (PHI). Your child cannot participate in the study if you choose not to share his/her PHI. You may refuse to permit or cancel permission regarding the disclosure of your child's PHI, however, his/her part in the study will then end.

### Use of Health Information by Nemours Staff

The health information that will be used within Nemours includes all data collected for this study, as described in Section 9 of this form. In addition, researchers may ask your permission to request your child's health care records from their other health care providers.

Your child's identity will be protected as much as possible. Nemours protects you and your child's health information by storing records in files or computers that can only be used by authorized Nemours staff. Study staff will assign your child a unique number and special code that will be used in place of their name. All of your child's data will also be given this code. When the study is complete the link to your child's identification and his/her ID code will be removed.

After this study is over, we will remove all information from the samples that could be used to identify your child. This is done to keep your child's health information private. After this happens, we will not know which samples belonged to your child. This means that if you decided you wanted to have your child's samples destroyed, we would not be able to do so because we would not know which ones belonged to your child.

The people within Nemours that may use this health information include:

- The investigators listed on the first page of this permission form and their staff,
- The Nemours Institutional Review Board (IRB) (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;



Abbreviated Study Title: LASST

- Nemours internal audit staff.

**Disclosure of Health Information to Others**

Information from this research study will also be contained in your child's Nemours' medical record if they are seen at Nemours, along with the information about your child's regular office visits. This will help other doctors to know about the research study your child is in and give them extra information from the research that might help them take better care of your child. The same information might also be seen by anyone who can look at your child's medical records, such as your insurance company.

Identifiable health information will be given (disclosed) to the following individuals or groups:

- SPONSORS: American Lung Association Asthma Clinical Research Center (ALA-ACRC), and GlaxoSmithKline.

The PHI that will be given (disclosed) to people or groups outside of Nemours for research purposes are checked in the table below:

Type of Identifiable Health Information:	Disclosed
History and Physical	<input checked="" type="checkbox"/>
Results of Procedures	<input checked="" type="checkbox"/>
Demographics (information about race, ethnicity, gender, age, DOB)	<input checked="" type="checkbox"/>
Questionnaires	<input checked="" type="checkbox"/>
Routine lab results	<input checked="" type="checkbox"/>
Alpha-numeric code (using participants initials)	<input checked="" type="checkbox"/>

**Limits on Protection of Privacy and Confidentiality**

Only health care organizations have to follow laws and rules about protecting the privacy of health information. If health information containing peoples' identities is given to other kinds of companies or organizations, they are not required by law to safeguard the privacy and confidentiality of that information. Nemours expects these companies and organization to protect the privacy and confidentiality of research participants, but it is not possible for Nemours researchers to assure that this happens.

Government agencies that may look at records for this research study, including the above health information, include:

- The U.S. Food and Drug Administration
- The U.S. Department of Health and Human Services
- Other agencies of State and local government as required by law

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

**20. WHO CONTROLS AND OWNS THE SAMPLES?**

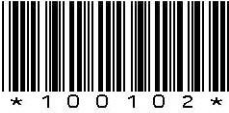
Scientists at Nemours work to find the causes and cures of disease. The data, blood, and specimens collected from your child during this study are important to both this study and to future research. Should you decide to donate your child's DNA for genetic testing their DNA sample will remain in possession of the American Lung Association and will be stored at Nemours Children's Clinic in Jacksonville, FL. The results of the research on these samples might be valuable for commercial and/or intellectual property (for example, patent) purposes. If



Approved by the Nemours IRB:

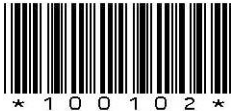
Valid from: 09/04/2015 through 09/03/2016

IRB# JAX: 288148



Abbreviated Study Title: LASST

you decide to allow your child to participate in this genetic research, you are giving your child's sample to the American Lung Association. The American Lung Association retains sole ownership of the research results, and of any use or development of the research records (including your child's sample) consistent with this consent. You will not receive any financial benefit that might come from the research results.



Abbreviated Study Title: LASST

**21. SIGNATURES:**

I am making a decision whether or not to permit my child to participate in this study. I understand that my child may also have to agree to participate in the study before he/she will be allowed to be in this study. I have read this form, or have had it read to me in a language that I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw permission for participation in this study and for the use and/or disclosure of PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and/or disclosure of my child's PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw permission, the use and/or disclosure of PHI described in this form will not have an expiration date.
- My child's PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this permission form.
- If I refuse to sign this permission form, my child will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my child's protected health information.
- I have the right to revoke my permission for the use and disclosure of my child's health information at any time, which would end his/her participation in this study.
- I will receive a signed and dated copy of this form.

My signature indicates that:

- As his or her parent or guardian, I give my permission for the minor child named below to participate in the research study described in this Parental Permission Form.
- I give the researchers and Nemours permission to use and/or disclose my child's individually identifiable health information for this research study as described in Section 19.

\_\_\_\_\_  
Name of Participant (Print)

\_\_\_\_\_  
Participant Date of Birth:

\_\_\_\_\_  
Signature of  
Parent / Guardian

\_\_\_\_\_  
Printed Name of  
Parent / Guardian

\_\_\_\_\_  
Date

Check Relation to Participant: ☐ Parent ☐ Guardian: (Guardians must have documented authority to give permission for participation in a research study according to the laws of the State in which the treatment occurs.)

I the undersigned, certify that to the best of my knowledge the parent/legal representative signing this permission had the study fully and carefully explained and that he/she understands the nature, risks and benefits of participation in this research study.

\_\_\_\_\_  
Name of Person Obtaining  
permission (Investigator or Designee)

\_\_\_\_\_  
Signature of Person Obtaining  
permission

\_\_\_\_\_  
Date

Copy of the signed form was provided to Parent/ Guardian on [Date] \_\_\_\_\_



Abbreviated Study Title: LASST

**NEMOURS**  
**ADDENDUM FOR *OPTIONAL* TESTING OR FUTURE USE OF SAMPLES OR DATA**  
*Version February 2014*

A. Sharing spirometry results with primary asthma care doctor:

☐ \_\_\_\_\_ Yes, please send my child's results to the doctor listed below:

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☐ \_\_\_\_\_ No, do NOT send my child's results to his/her doctor.**B. Future Testing:**

DNA is material that contains information about our ancestors that may play a role to help in determining whether someone gets asthma, how severe the asthma may be, and the response to asthma treatments. Your decision to allow your child to provide blood for future DNA testing is voluntary and will not influence his/her ability to participate in the study. We will draw 10 mL (2 teaspoons) of blood for this test. We will isolate DNA (genetic material) in the blood to test if genes influence response to asthma drugs used in this study. If your child participates in the genetic study, then the blood sample and DNA will be used for future studies including future genetic studies of asthma. Because of confidential coding of specimens, you will not be notified of individual results from DNA tests and no results will appear in your study records or medical records. After this study is over, we will remove all information from the samples that could be used to identify your child. This is done to keep your child's health information private. After this happens, we will not know which samples belonged to your child. This means that if you or your child wanted to have your child's samples destroyed, we would not be able to do so because we would not know which sample(s) belonged to your child.

There is the possibility that someone you did not approve sees and uses your child's DNA information. To guard against this, your child's blood samples will be identified only by a number code and no tests will be done except for those associated with asthma and airway disease.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), reduces the risk of discrimination by health insurance companies, group health plans, and most employers based on your (child's) genetic information.

**NOTIFICATION FOR FLORIDA RESIDENTS:**

By Florida law, the results of any DNA analysis, which includes DNA typing and genetic testing, are the exclusive property of the person tested, and may not be disclosed without your permission (as provided in this form). Nemours is notifying you that the DNA analysis described in this document will be performed as described, and results will be provided to those individuals and / or groups noted in the section on 'use and disclosure of PHI'. At your request, Nemours will provide the results of DNA analysis that it receives to your child's primary care physician. The DNA analysis is performed strictly for research purposes and will not be used in any decision regarding insurability, employment, mortgage, loan, credit or education opportunity.

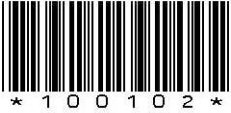




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Please indicate below whether you wish to have your child's blood drawn for DNA genetic testing as described above.

I agree to allow my child to provide blood for DNA for use in this study and to be stored for possible future genetic analysis:

☐ Yes Initials \_\_\_\_\_

☐ No Initials \_\_\_\_\_